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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/588,293	05/16/2007	Ralf Dunkel	2400.0660000/VLC/L-Z	7192	
	7590 12/02/200 SLER, GOLDSTEIN &		EXAMINER		
1100 NEW YO	00 NEW YORK AVENUE, N.W. ASHINGTON, DC 20005			RODRIGUEZ-GARCIA, VALERIE	
WASHINGTO	N, DC 20005	ART UNIT		PAPER NUMBER	
			1626		
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			12/02/2008	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)					
Office Action Comment	10/588,293	DUNKEL ET AL.					
Office Action Summary	Examiner	Art Unit					
	VALERIE RODRIGUEZ-GARCIA	1626					
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence ad	ldress				
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 6(a). In no event, however, may a reply be tim rill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONEI	I. lely filed the mailing date of this coorsists U.S.C. § 133).					
Status							
1) Responsive to communication(s) filed on							
	-· action is non-final.						
· <u> </u>		socution as to the	n morite ie				
	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
closed in accordance with the practice under L	x parte Quayle, 1900 C.D. 11, 40	.J. O.G. 213.					
Disposition of Claims							
4)⊠ Claim(s) <u>1-11</u> is/are pending in the application.							
4a) Of the above claim(s) is/are withdrawn from consideration.							
5) Claim(s) is/are allowed.							
6)☐ Claim(s) is/are rejected.							
7) Claim(s) is/are objected to.	· · · · · · · · · · · · · · · · · · ·						
8) Claim(s) <u>1-11</u> are subject to restriction and/or e	election requirement.						
Application Denova							
Application Papers							
9) The specification is objected to by the Examine							
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.							
Applicant may not request that any objection to the							
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).							
11)☐ The oath or declaration is objected to by the Ex	aminer. Note the attached Office	Action or form P1	ГО-152.				
Priority under 35 U.S.C. § 119							
12)☐ Acknowledgment is made of a claim for foreign	priority under 35 U.S.C. § 119(a)	-(d) or (f).					
·—	a) ☐ All b) ☐ Some * c) ☐ None of:						
<ol> <li>Certified copies of the priority documents</li> </ol>	s have been received.						
<ol><li>Certified copies of the priority documents</li></ol>	s have been received in Application	on No					
3. Copies of the certified copies of the priority documents have been received in this National Stage							
application from the International Bureau (PCT Rule 17.2(a)).							
* See the attached detailed Office action for a list of the certified copies not received.							
Attachment(s)							
1) Notice of References Cited (PTO-892)	4) Interview Summary						
Notice of Draftsperson's Patent Drawing Review (PTO-948)     Information Disclosure Statement(s) (PTO/SB/08)	Paper No(s)/Mail Da 5) Notice of Informal P						
Paper No(s)/Mail Date	6) Other:	1 1					

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1. This application is a 371 of PCT/EP05/00629 filed on 01/22/2005, which claims foreign priority to 102004005785.0, filed 02/06/2004.

Claims 1-11 are pending.

## Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-2, 4 and 8-11, drawn to products, classified in various subclasses of classes 514, 544, 546 and 548. Further restriction based on the election may be made.

Group II, claim(s) 3, drawn to process for preparing product of Formula I, classified in various subclasses of classes 514, 544, 546 and 548. Further restriction based on the election may be made.

Group III, claim(s) 5-6, drawn to methods of use product of Formula I, classified in various subclasses of class 514.

Group IV, claim(s) 7, drawn to process for preparing compositions, classified in various subclasses of class 514.

Application/Control Number: 10/588,293

Art Unit: 1626

The inventions listed as Groups I-IV do not relate to a single general inventive concept under 35 USC 121 or PCT Rule 13.1 because they lack the same or corresponding special technical features:

In this case, they do not share the same essential structural element(s) that define the "special technical feature" necessary to specify a contribution over the prior art. The compound of formula I, with its many and distinct variables, results in so many permutations that no common core can be constructed, thus the lack of a special

technical feature is apparent.

There is no special

Page 3

technical feature defining a contribution which each of the inventions, considered as a whole, makes over the prior art. Therefore, the claims are not so linked by a special technical feature within the meaning of PCT Rule 13.2 so as to form a single inventive concept, and unity between Groups I-IV and between Markush species is broken.

Each invention listed above is directed to or involves the use of compounds which are recognized in the art as being distinct from one another because of their diverse chemical structure, their different chemical properties, modes of action, different effects and reactive conditions (MPEP 806.04, MPEP 808.01). Additionally, the level of skill in the art is not such that one invention would be obvious over the other invention (Group), i.e. they are patentable over each other. Chemical structures, which are similar, are presumed to function similarly, whereas chemical structures that are not similar are not presumed to function similarly. The presumption even for similar

Art Unit: 1626

chemical structures though is not irrebuttable, but may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have bee expected to function as the structure of the claimed invention. Note that in accordance with the holding of Application of Papesch, 50 CCPA 1084, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) and In re Lalu, 223 USPQ 1257 (Fed. Cir. 1984), chemical structures are patentably distinct where the structures are either not structurally similar, or the prior art fails to suggest a function of a claimed compound would have been expected from a similar structure.

## **Election of Species**

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Regardless of Group elected, an election of a single compound is further required, including an exact definition of each substitution on the base molecule (Formula (I)), wherein a single member at each substituent group or moiety is selected. For example, if a base molecule has a substituent group R, wherein R is recited to be any one of C<sub>1-8</sub>alkyl, C<sub>1-6</sub>alkylsulphinyl, C<sub>1-6</sub>alkylsulphonyl, C<sub>1-6</sub>haloalkylthio, etc., then applicant must select a single substituent for R, for example C<sub>1-6</sub>haloalkylthio, <u>and</u> each subsequent variable position. A drawing of the exact chemical structure is required.

The reply must also identify the claims readable on the elected species, including

any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Where an election of Group I is made, upon election of a single compound, the Office will review the claims and disclosure to determine the scope of the independent invention encompassing the elected compound (compounds which are so similar thereto as to be within the same inventive concept and reduction to practice). The scope of an independent invention will encompass all compounds within the scope of the claim, which fall into the same class and subclass as the elected compound, but may also include additional compounds, which fall in related subclasses. Examination will then proceed on the elected compound AND the entire scope of the invention encompassing the elected compound as defined by common classification. A clear statement of the examined invention, defined by those class(es) and subclass(es) will be set forth in the first action on the merits. Note that the restriction requirement will not be made final until such time as applicant is informed of the full scope of compounds along with (if appropriate) the process of using or making said compound under examination. This will be set forth by reference to specific class(es) and subclass(es) examined.

Art Unit: 1626

All compounds falling outside the class(es) and subclass(es) of the selected compound and any other subclass encompassed by the election above will be directed to nonelected subject matter and will be withdrawn from consideration under 35 U.S.C. 121 and 37 C.F.R. 1.142(b). Applicant may reserve the right to file divisional applications on the remaining subject matter. (The provisions of 35 U.S.C. 121 applies with regard to double patenting covering divisional applications.)

If desired upon election of a single compound, applicants can review the claims and disclosure to determine the scope of the invention and can **set forth** a group of compounds, which are so similar within the same inventive concept and reduction to practice. Markush claims must be provided with support in the disclosure for each member of the Markush group. See MPEP 608.01(p). Applicant should exercise caution in making a selection of a single member for each substituent group on the base molecule to be consistent with the written description.

The species included in the above inventions do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

a)Each chemical species is a distinct chemical lacking a special technical feature in view of the facts that the compound of formula I, with its many and distinct variables, results in so many permutations that no common core can be constructed.

The examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and a product claim is

Page 7

subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is *presented prior to* final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be **allowable**, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai; In re Brouwer and 35 U.S.C.§ 103(b)," 1184 O.G. 86 (March 26, 1996).

Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include all the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01. Filing of appropriate terminal disclaimer in anticipation of a rejoinder may speed prosecution and the process of rejoinder.

4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence

or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

## Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VALERIE RODRIGUEZ-GARCIA whose telephone number is (571)270-5865. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

Application/Control Number: 10/588,293 Page 10

Art Unit: 1626

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

VRG 1626 /Kamal A Saeed/ Primary Examiner, Art Unit 1626